



Oxford Lasers Ltd. Newtec Place  
Magdalen Road, Oxford OX4 1RD  
Tel: (0865) 251479  
Fax: (0865) 790619

13 October 1992

LET'S MANAGEMENT BRAND  
93 AUG 18 AM 9:35

Jerome E. Dennis  
Light Products Branch  
**HFZ-312**  
Center for Devices and Radiological Health  
1390 Piccard Drive  
**Rockville**  
MD 20750  
USA

Dear Sir,

Thank you for sending us the notice of consideration of possible amendments to the laser performance standard. As a European manufacturer exporting to the US we very much welcome the proposal of increased harmonisation with **IEC825**. The lasers we manufacture are all Class IV and so the main changes that will affect us are point 9 on safety interlocks and points 13-15 on **labelling**.

As you comment in point 9, safety interlocks are not now required by **IEC825** on Class IV lasers on the grounds, presumably, that the hazard inside the laser is no worse than the hazard presented by the beam itself. I must say that I found this surprising and consider that lifting the lid of the laser box whilst the laser is running should not expose the user to laser radiation above Class 1. This could be achieved either by interlocking the lid so that the laser turns off, or by fully enclosing the beam within the box. The beam should be enclosed inside a cover which is either interlocked itself or which requires a tool to remove it.

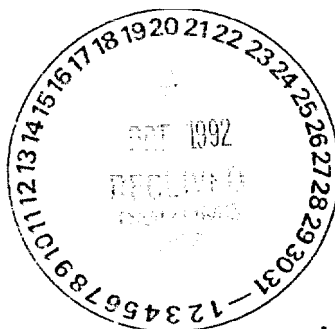
It would be very helpful if the FDA regulations and the **IEC** regulations had the same view on what constituted safe practice in this regard. Manufacturers would of course design their product to satisfy the most stringent of the two codes so very little is achieved by having different regulations.

An agreement that the same labels can satisfy the requirements in the US and Europe would also be very helpful to us.

I look forward to receiving the new regulations in due course.

Yours faithfully,

Rhys Lewis - 5  
PRODUCT DEVELOPMENT MANAGER



OXFL  
27809  
22-1  
83N-0044

LPB-DMS - 10/20/92  
JAS  
C9

IMAG

XXX XX . XXX XXXXXXXX XXXXXXXXXX XX XX XXX XX XXX XXXXXXXXXX  
 XXX XXX XXX XXXXXXXXXX XXXXXXXXXX XXX XXX XXX XXX XXXXXXXXXX  
 XXX XXXX XXX XXX XXX XXX XXX XXX XXX XXX XXX XXXXXXXXXX  
 XXX XXXXX XXX XXX XXX XXX XXX XXX XXX XXX XXX XXX XXX  
 XXX XXXXXXXXXX XXX XXX XXX XXX XXX XXX XXX XXX XXX XXX 1026  
 XXX XXX XXXXX XXX XXX XXX XXX XXX XXX XXX XXX XXX XXX  
 XXX XXX XXXX XXX XXX XXX XXX XXX XXX XXX XXX XXX XXX M9M  
 XXX XXX XXX XXXXXXXXXX XXXXXXXXXX XXX XXX XXX XXX XXX XXXXXXXXXX  
 XXX XXX XX XXXXXXXXXX XXXXXXXXXX XXX XXX XXX XXX XXX XXXXXXXXXX

FROM	OXFORD LASERS, LTD. (OXFL) - LEWIS		DATE	10/13/92
SUBJ	THANKING OCS FOR SENDING US THE NOTICE OF CONSIDERATION OF POSSIBLE AMENDMENTS TO THE LASER PERFORMANCE STANDARD.			
CNTL NO	228721	FILE PNTS	OXFL/L1	RECD
				10/20/92

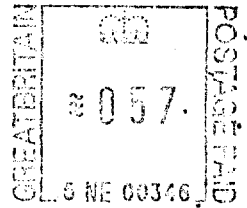
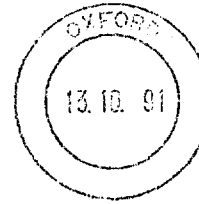
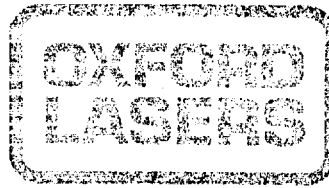
INCOMING ROUTE SHEET, OFFICE OF COMPLIANCE, DEVICES AND RADIOLOGICAL HEALTH

ROUTE TO	UNIT	INITIALS	DATE	COMMENTS:
JERRY DENNIS	LPB			

NOTE: UNLESS OTHERWISE MARKED, THE ATTACHED IS AN ACTION COPY AND NEED NOT BE RETURNED TO FILE. IF FILE POINT CHANGES ARE NECESSARY, NOTE THEM ON THIS SHEET, THEN RETURN IT OR A PHOTOCOPY TO THE DMS FILE STAFF.

XXXXXX XXXXXX XXXXXX XXXXXXXXXXXX XXXXXX XX  
 XXXXXXXXXXX XXXXXXXXXXX XXXXXXXXXXX XXXXXXXXXXX XXXX  
 XXX XXX XXX XXX XXX XXX XXX XXX XXX XXX XXX  
 XXX XXX XXX XXX XXX XXX XXX XXX XXX XXX XXX  
 XXX XXX XXX XXX XXX XXX XXX XXX XXX XXX XXX  
 XXX XXX XXX XXX XXX XXX XXX XXX XXX XXX XXX  
 XXX XXX XXX XXX XXX XXX XXX XXX XXX XXX XXX  
 XXX XXX XXX XXX XXX XXX XXX XXX XXX XXX XXX  
 XXX XXX XXX XXX XXX XXX XXX XXX XXX XXX XXX  
 XXX XXX XXX XXX XXX XXX XXX XXX XXX XXX XXX

VIA AIR MAIL



Jerome E. Dennis  
Light Products Branch  
HFZ-312  
Center for Devices and Radiological Health  
1390 Piccard Drive  
Rockville  
MD 20750  
USA

Int'l. Telecommunication Union